



American Surgical Products

Product Description:

The ASP Distraction Screws are available in three screw lengths (12mm, 14mm, and 16mm) and are supplied sterile, 1 screw per pouch and 5 pouches per box. REF #'s are: ASP12S (12mm Screws), ASP14S (14mm Screws), and ASP16S (16mm Screws).

The ASP Distraction Screws are intended for the distraction in the anterior approach to the cervical spine from C2 thru C7. Product is intended to be used by trained surgeons and is designed for use with compatible distractors and screwdrivers.

Instructions for use:



- 1) Inspect package prior to use and do not use if the package is damaged or sterility has been compromised.
- 2) Select the desired length of distraction screw. The length should be chosen based on patient anatomy and surgeon experience.
- 3) Start with a pilot hole using the Twist Drill or the Twist Drill with handle.
- 4) Drill through the Drill Guide.
- 5) Using the Distraction Screw Driver screw the distraction screw thru the drill guide until two fingers tighten or until screw is fully seated.
- 6) Repeat steps 1 thru 4 for the placement of the 2nd screw.
- 7) Remove the screwdriver and drill guide
- 8) The above procedure ensures parallel placement of the distraction screws. Do not bend the pins after insertion as this may cause failure of the screw!
- 9) Place appropriate distractor over the distraction screws and open as required.
- 10) Remove distraction screws after use with the Distraction Screw Driver.
- 11) Dispose of the distraction screw in an approved sharps container.
- 12) If needed, the screw or any fragment thereof can be located by means of an X-Ray.



Warnings/Precautions:



- 1) CAUTION: US Federal law restricts this device to sale by or on the order of a physician.
- 2) Do not reuse. Reuse may compromise the structural integrity of the device and/or lead to device failure. Reuse also presents biological hazards associated with disease transmission and immune/allergy issues, some of which could cause severe illness or be fatal.
- 3) Do not bend the pins after insertion as this may cause failure of the screw.
- 4) The decision to use Distraction Screws is based upon suitability of patient bone condition.

Company Information:

For more information on this product or any products mentioned in this IFU please contact:

American Surgical Products (ASP)

7491 N Federal Hwy, Ste C5125

Boca Raton, FL, 33487

P: 1-866-573-7774

F: 1-800-801-5975